THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YUKIO SHIMAZAKI, NOBUHIRO KAWASHIMA, MIKI SUZUKI YASUHITO TANAKA, RYO TANAKA, KIYOSHI SAKAI, HISAHIRO ISHIWARI

Appeal No. 1997-0472
Application 08/259,152

ON BRIEF

Before KIMLIN, JOHN D. SMITH and WALTZ, Administrative Patent Judges.

KIMLIN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 26-32, all the claims remaining in the present application. Since the examiner has withdrawn the rejection of claim 31[1], the instant appeal involves only claims 26-30 and 32. Claim 26 is illustra-tive:

[1] See page 2 of the answer.

26. An aqueous solution consisting essentially of

(1) t-PA and

(2) an anionic polymer or a salt thereof,

said aqueous solution having a pH in the range of within -2 to +2 pH units from the isoelectric point of the t-PA and an ionic strength of at most 0.05 mol/R,

said t-PA prior to dissolution in said aqueous solution having a solubility of at most 2.0 mg/ml measured at a pH of about 7.3 in a 1/15 M phosphate buffer solution,

whereby the solubility of said t-PA is increased, with the use of said anionic polymer or said salt thereof, to a degree such that said t-PA is dissolved in said aqueous solution.

The examiner relies upon the following reference as evidence of obviousness:

Dussourdd'Hinterland, et al. (D'H) 4,083,961 Apr. 11, 1978

The appealed claims are directed to an aqueous solution consisting essentially of tissue-type plasminogen activator (t-PA) and an anionic polymer, such as dextran sulfate or a salt thereof. According to appellants, it is known in the art that t-PA is extremely insoluble, whereas "[t]he claimed compositions provide t-PA in a form suitable for use which

remain soluble even in relatively low salt concentrations" (page 4 of brief).

Appellants submit at page 2 of the brief that "[t]he rejected claims do not stand or fall together" and that "[e]ach claim is believed to define a separately patentable invention." However, the ARGUMENTS section of appellants' brief fails to advance any argument that is reasonably specific to any particu-lar claim on appeal. Accordingly, all the appealed claims stand or fall together with claim 26.

Appealed claims 26-30 and 32 stand rejected under 35 U.S.C. § 103 as being unpatentable over D'H.

We have thoroughly reviewed each of appellants' arguments for patentability. However, we concur with the examiner that the claimed subject matter would have been obvious to one of ordinary skill in the art within the meaning of § 103 in view of the applied prior art. Accordingly, we will sustain the examiner's rejection.

Appellants do not dispute the examiner's factual determina-tion that D'H discloses an aqueous solution of a plasminogen activator and appellants' anionic polymer, dextran

sulfate, having a pH within the claimed range. Appellants' principal contention is that "the plasminogen activator of D'H is urokinase

while that of the present invention is t-PA (urokinase is an entirely different protein from t-PA)" (page 5 of brief). On the other hand, it is the examiner's position that D'H discloses solutions of an anionic polymer and plasminogen activator in general, i.e., the reference is not limited to solutions of urokinase.

Our review of the reference disclosure requires us to reject appellants' argument that the plasminogen activator of D'H is urokinase. In the description of the prior art at column 1, lines 15 et seq., D'H discloses that urokinase is very sensitive and its effect is diminished very quickly on inhibition, whereas U.S. Patent No. 3,998,947 describes "a process for extracting a novel plasminogen activator from animal organs which was at least equivalent to urokinase in regard to activity but which was unaffected by inhibitors." In the next sentence, the reference discloses that "[t]he

Applicants have now found that the activity of plasminogen activators and particularly the plasminogen activator prepared by the process claimed is (sic: in) U.S. Serial No. 529,147 [U.S. Patent No. 3,998,947], may be powerfully potentiated by combining it with a polysaccharide sulphate."

From this reference disclosure it is clear to us that the plasminogen activator described by D'H is a "novel" one and not urokinase. Furthermore, our review of U.S. Patent No. 3,998,947 reveals that the activator described in the '947 patent is a "tissular, endocellular plasminogen activator extracted from the organs of animals" (column 1, lines 19-21). Hence, from our perspective, the conclusion is inescapable that the plasminogen activator of D'H is of the tissue-type and, therefore, not distinguishable from the presently claimed t-PA.

Appellants also maintain that "in D'H polysaccharide sulphate is added for the purpose of **precipitating** urokinase, not for dissolving urokinase" and "the objective of D'H is to **improve the activity** of urokinase" (page 5 of brief).

However, as noted by the examiner, the reason that D'H forms an aqueous solution of a plasminogen activator and an anionic polymer is not germane to the patentability of the claimed composition.

We note that one of the present inventors, Yukio Shimazaki, filed a declaration under Rule 132 on June 13, 1994. However, since appellants' brief makes no reference to the declaration and bases no argument thereon, we have assigned no probative value to

the Declaration in reaching our conclusion of obviousness for the claimed subject matter.

One final point remains. Since we find that D'H discloses an aqueous solution comprising appellants' t-PA and anionic polymer, we invite the examiner to reconsider the allowability of claim 31 which is drawn to a method of increasing the solubility of t-PA in aqueous solution by adding an anionic polymer to the solution. It would seem that D'H describes or, at least, renders obvious the claimed method of adding an anionic polymer to an aqueous solution of t-PA,

regardless of whether the reference teaches that such method increases the solubility of t-PA. For the proposition that the introductory claim language "[a] method for increasing the solubility of t-PA" does not serve to patentably distinguish the claimed method from the prior art method of formulating an aqueous solution, the examiner is invited to review the analysis articulated in In re Tomlinson, 363 F.2d 928, 934, 150 USPQ 623, 628 (CCPA 1966).

In conclusion, based on the foregoing, the examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

EDWARD C. KIMLIN)
Administrative Patent Judge)
)

JOHN D. SMITH Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
THOMAS A. WALTZ Administrative Patent Judge	)	

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Nixon & Vanderhye
1100 North Glebe Road
8th Floor
Arlington, VA 22201-4714